



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

April 22, 2002

Mr. Ka Nin Lee, Owner
KA NIN LEE d.b.a. SOYFOODS OF AMERICA
1091 East Hamilton Road
Duarte, CA 91010-2743

W/L Number: 37 - 02

Dear Mr. Lee,

The Food and Drug Administration (FDA) conducted an inspection of your food manufacturing firm located at 1091 East Hamilton Road, Duarte, California on March 20 and 21, 2002. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed) which delineated a number of insanitary conditions observed in your food manufacturing firm at the time of the inspection. These conditions cause the food products stored in your food manufacturing firm to be adulterated within the meaning of Section 402(a)(4) (copy enclosed) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. Your tofu products could be considered high-risk food articles in that this type of food can easily serve as a growth media for pathogenic microorganisms that cause foodborne illness. The criteria and definitions in the Good Manufacturing Practices (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110, apply in determining whether a food is considered adulterated. You can also find links to the Act and regulations at FDA's website at www.fda.gov

The following insanitary conditions were observed by the investigators during the inspection:

1. A knife lying in a pool of water on the processing room floor was picked up and used to cut tofu, without any cleaning and sanitizing of the knife.
2. A vacuum hose used to pump soybeans between soaking bins and hoppers for the grinders was observed lying on the floor in standing water, and then put into use without being cleaned and sanitized. Other hoses for use in filling soaking bins, and rinsing equipment and utensils, were observed lying on the floor, often in pooled water.

3. No back flow prevention or anti-siphon devices were present on any of the five hose spigots in the processing rooms, and during the inspection, cleaning hoses without any nozzles were often left on the processing room floor in pools of standing water.
4. Employees were observed handling in-process and finished products with their bare hands directly after handling insanitary objects without washing and sanitizing their hands. One employee was observed packing finished baked tofu with her bare hands after moving milk crates and other equipment, without washing and sanitizing her hands. Another employee was observed handling and cutting tofu with her bare hands while wearing a ring.
5. Food residue was observed in several places where direct contact with processed food was possible: on the rollers on the table used to mold the tofu, on the magnetic knife holder, and on air vent covers and racks directly over the steam evaporation tables with strips of tofu stored along the racks under this area. Residues were also observed on employees' aprons which had not been cleaned and sanitized from the previous day's use.
6. Dirty water was observed in the single compartment sink used to soak and wash utensils and equipment, and this water was not changed from 8:00 a.m. through 3:00 p.m. on one day of the inspection.

In addition to the above insanitary conditions and practices, we also observed that toxic sanitizing agents were stored in the processing areas, without appropriate identifying labeling. For example, pump sprayers containing concentrated chlorine solution were observed sitting in the main processing room without any identifying labeling, and an unlabeled tub containing iodine solution was observed sitting on a crate next to the walk-in convection oven.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with the Act. You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before your response is due, please explain the reason for your delay and state when you will correct any remaining deviations.

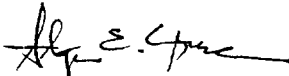
Please send your reply to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

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KA NIN LEE d.b.a. JOYFOODS OF AMERICA
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If you have questions regarding any issue in this letter, please contact Scott Goff, Compliance Officer at telephone number 949-798-7644

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse".

Alonza E. Cruse
District Director

Enclosures:

Form FDA 483
21 CFR PART 110
Section 402(a)(4) of the FD&C Act